

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN
USED ACCORDING TO DIRECTIONS**

2851. Adulteration and misbranding of dextrose in isotonic solution of three chlorides (Ringer's solution), and dextrose in isotonic solution of sodium chloride. U. S. v. Cutter Laboratories, Inc. Plea of nolo contendere. Fine, \$600. (F. D. C. No. 26708. Sample Nos. 350-K, 745-K, 746-K, 10453-K, 10454-K, 16248-K to 16250-K, incl., 16252-K, 24622-K, 36797-K.)

INFORMATION FILED: May 25, 1949, Northern District of California, against Cutter Laboratories, Inc., Berkeley, Calif.

ALLEGED SHIPMENT: Between the approximate dates of October 16, 1947, and March 18, 1948, from the State of California into the States of Georgia, Florida, New Jersey, Illinois, and Washington.

NATURE OF CHARGE: Adulteration, Section 501 (b), the *dextrose in isotonic solution of sodium chloride* purported to be, and was represented as, "Dextrose and Sodium Chloride Injection," a drug the name of which is recognized in the U. S. Pharmacopoeia, and its quality and purity fell below the official standard since it was not sterile but was contaminated with viable micro-organisms; and the difference in quality and purity of the article from the standard was not plainly stated or stated at all on its label.

Adulteration, Section 501 (c), the purity and quality of the *dextrose in isotonic solution of three chlorides (Ringer's solution)* fell below that which it purported and was represented to possess since it purported and was represented to be sterile and suitable and appropriate for intravenous administration, whereas it was not sterile and was not suitable and appropriate for intravenous administration since it was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the statement "A safe, sterile * * * solution" borne on the labels of the articles was false and misleading since the articles were not sterile and were not safe for use since they were contaminated with viable micro-organisms; and, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency and duration suggested in the labeling since the articles were contaminated with viable micro-organisms.

DISPOSITION: June 24, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$600.

2852. Misbranding of syrup urethane. U. S. v. 9 Jugs, etc. (F. D. C. No. 26859. Sample No. 34272-K.)

LIBEL FILED: March 14, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about October 29 and November 17 and 27, 1948, and January 10, 1949, by Marvin R. Thompson, Inc., from Stamford, Conn.

PRODUCT: 9 1-gallon jugs and 24 1-pint bottles of *syrup urethane* at San Francisco, Calif.

LABEL, IN PART: "Syrup Urethane-M. R. T. * * * Each Teaspoonful (5-cc) contains Urethane 4 Grs. in a Flavored Syrup Base. Directions: 1 teaspoonful every 3 or 4 hours, or as directed by the physician."